UNITED STATES DISTRICT COURT
DISTRICT OF MINNESOTA

TRISTA A. HOOT-COMTOIS, Plaintiff, v. BAYER HEALTHCARE PHARMACEUTICALS, INC. and BAYER PHARMA AG, Defendants.	Court File No. _____ **COMPLAINT AND DEMAND FOR JURY TRIAL**

Plaintiff Trista A. Hoot-Comtois ("Plaintiff"), by and through Plaintiff's attorneys of record, Charles H. Johnson and Jonathan R. Mencel, hereby files this Complaint and Demand for Jury Trial against Defendants Bayer HealthCare Pharmaceuticals, Inc. and Bayer Pharma AG (collectively "Defendants"), and states on information and belief as follows:

JURISDICTION AND VENUE

1. This Court has jurisdiction over this action pursuant to 28 U.S.C. § 1332 because Plaintiff alleges that the amount in controversy exceeds seventy-five thousand dollars ($75,000), exclusive of interest and costs, and there is complete diversity of citizenship.

2. Venue in this Court is proper in that Bayer HealthCare Pharmaceuticals, Inc. and Bayer Pharma AG researched, designed, licensed, manufactured, tested, marketed, distributed, and/or sold the prescription drug Yaz/Yasmin in the State of Minnesota. Thus, a sufficient nexus exists between Defendants' forum contacts and Plaintiff's claims to justify this venue and the assertion of jurisdiction in Minnesota.

NATURE OF THE ACTION

3. This is an action for strict products liability, breach of express and implied warranty, negligence, negligence *per se*, fraudulent misrepresentation, fraudulent concealment, fraud, negligent misrepresentation, and unjust enrichment brought by Plaintiff individually for damages associated with her ingestion of the pharmaceutical drug YAZ/Yasmin, also known generically as drospirenone and ethinyl estradiol (hereinafter collectively referred to as "Yaz/Yasmin").

4. Defendants, Bayer HealthCare Pharmaceuticals, Inc. and Bayer Pharma AG (hereinafter collectively referred to as "Defendants") designed, researched, manufactured, tested, advertised, promoted, marketed, sold, and distributed YAZ/Yasmin.

5. When warning of safety and risks of YAZ/Yasmin, Defendants negligently and/or fraudulently represented to the medical and healthcare community, the Food and Drug Association (hereinafter referred to as "FDA"), to Plaintiff and the public in general, that YAZ/Yasmin had been tested and was found to be safe and/or effective for its indicated use.

6. Defendants concealed their knowledge of YAZ/Yasmin's defects, from Plaintiff, the Food Drug Administration, the public in general and/or the medical community specifically.

7. These representations were made by Defendants with the intent of defrauding and deceiving Plaintiff, the public in general, and the medical and healthcare community in particular, and were made with the intent of inducing the public in general, and the medical community in particular, to recommend, dispense and/or purchase YAZ/Yasmin for use as a contraceptive, all of which evinced a callous, reckless, willful, depraved indifference to health, safety and welfare of the Plaintiff herein.

8. Defendants negligently and improperly failed to perform sufficient tests, if any, on women using YAZ/Yasmin during clinical trials, forcing Plaintiff, and her physicians, hospitals, and/or the FDA, to rely on safety information that applies to other oral birth control medications, which does not entirely and/or necessarily apply to the YAZ/Yasmin whatsoever.

9. Defendants were negligent in failing to adhere to and/or take into consideration warnings from the FDA, who determined that the Defendants were misleading the public in general, and the medical community in particular, through the use of advertisements which overstated the efficacy of YAZ/Yasmin and minimized the serious risks of the drug.

10. As a result of the defective nature of YAZ/Yasmin, those persons who use and/or used and relied on YAZ/Yasmin have suffered and/or are at a greatly increased risk of serious and dangerous side effects including, inter alia, heart arrhythmias, myocardial infarctions, and other adverse cardiovascular events including stroke, transient ischemic attack, blood clots, embolisms, gall bladder disease, and/or sudden death, as well as other severe and personal injuries which are permanent and lasting in nature, physical pain and mental anguish, including diminished enjoyment of life, and a future of high risk pregnancies.

11. Plaintiff has sustained certain of the above health consequences due to her use of YAZ/Yasmin.

12. Defendants concealed their knowledge of the defects in their products from the Plaintiff, and her physicians, hospitals, pharmacists, the FDA, and the public in general.

13. Consequently, Plaintiff seeks compensatory damages as a result of her use of the YAZ/Yasmin, which has caused, may cause, and/or will continue to cause Plaintiff to suffer and/or be at greatly increased risk of serious and dangerous side effects including, inter alia, heart arrhythmias, myocardial infarctions, and other adverse cardiovascular events including

stroke, transient ischemic attack, blood clots, embolisms, gallbladder disease and/or sudden death, as well as other severe and personal injuries which are permanent and lasting in nature, physical pain and mental anguish, including diminished enjoyment of life, and a future of high risk pregnancies.

PARTIES

14. Plaintiff at all times relevant is a citizen of the State of Vermont.

15. Defendant Bayer HealthCare Pharmaceuticals, Inc. is, and at all times relevant was, a corporation organized under the laws of the State of Delaware, with its principal place of business in the State of New Jersey.

16. Defendant Bayer Healthcare Pharmaceuticals, Inc. was formerly known as Berlex Laboratories, Inc., which was formerly known as Berlex, Inc., and Bayer Healthcare Pharmaceuticals, Inc. is the same corporate entity as Berlex, Inc. and Berlex Laboratories, Inc.

17. Defendant Bayer Healthcare Pharmaceuticals, Inc. researches, develops, manufactures and markets pharmaceutical products, including Yasmin and YAZ, an oral contraceptive.

18. At all relevant times, Defendant Bayer Healthcare Pharmaceuticals, Inc. has transacted and conducted business in the State of Minnesota, and derived substantial revenue by selling and distributing its products.

19. Defendant Bayer Pharma AG is a pharmaceutical company domiciled in Germany. Bayer Pharma AG was formerly known as Schering AG and Bayer Schering Pharma AG, and is the same corporate entity as Bayer Schering Pharma AG and Schering AG.

20. Defendant Bayer Pharma AG is the current owner of the patent(s) relating to the oral contraceptive, Yasmin.

21. Defendant Bayer Pharma AG is the current owner of the patent(s) relating to the oral contraceptive, YAZ.

22. Defendant Bayer Pharma AG manufactures drospirenone and ethinyl estradiol, the progestin and estrogen contained in YAZ, Yasmin, and Ocella.

23. At all relevant times, Defendant Bayer Pharma AG was in the business of and did design, research, manufacture, test, advertise, promote, market, sell and distribute YAZ/Yasmin for use as a combination oral contraceptive.

24. Defendant Bayer Pharma AG has transacted and conducted business in the State of Minnesota, and derived substantial revenue by selling and distributing its products.

FACTUAL BACKGROUND

25. At all relevant times, Defendants were in the business of and did design, research, manufacture, test, advertise, promote, market, sell, distribute, and/or have recently acquired the Defendants who have designed, researched, manufactured, tested, advertised, promoted, marketed, sold and distributed YAZ/Yasmin for use as a combination oral contraceptive.

26. Yasmin, the predecessor to YAZ, first received FDA approval in 2001 as a combination oral contraceptive.

27. Each tablet of Yasmin is composed of a combination of 3 mg of the progestin, drospirenone, and 0.03 mg of the estrogen, ethinyl estradiol.

28. YAZ received FDA approval in 2006 as a combination oral contraceptive.

29. YAZ is almost identical to Yasmin, but each tablet of YAZ is composed of the combination of 3 mg of the progestin, drospirenone, and only 0.02 mg of the estrogen, ethinyl estradiol.

30. YAZ and Yasmin are indicated for the prevention of pregnancy in women who use an oral contraceptive.

31. Combination birth control pills are referred to as combined hormonal oral contraceptives.

32. The difference between YAZ/Yasmin and other birth control pills on the market is that drospirenone has never been marketed in the United States and is unlike other progestins available in the United States.

33. In April 2002, the British Medical Journal reported that the Dutch College of General Practitioners recommended that older second generation birth control pills be prescribed in lieu of Yasmin as a result of 40 cases of venous thrombosis among women taking Yasmin.

34. In February 2003, a paper entitled *Thromboembolism associated with the new contraceptive YAZ/Yasmin* was published in the British Medical Journal detailing a Netherlands Pharmacovigilance Centre report of additional reports of thromboembolism where YAZ/Yasmin was suspected as the cause, including two deaths.

35. Adverse Event data maintained by the FDA indicate numerous serious Adverse Events including: heart arrhythmias, electrolyte imbalance, hyponatremis, hyperkalemia, hyperkalemic arrhythmias, atrial fibrillation, tachycardia, bradycardia, myocardial infarctions, stroke, transient ischemic attack, blood clots, embolisms, and/or sudden death.

36. Defendants have marketed their drug YAZ/Yasmin as effective for the treatment of premenstrual dysphoric disorder (hereinafter referred to as "PMDD"), premenstrual syndrome (hereinafter referred to as "PMS") and moderate acne, in addition to its FDA approved use as an oral contraceptive, and that it lacks certain side effects, such as weight gain, bloating and water retention, common to many other oral contraceptives.

37. Defendants have been warned at least three times by the FDA; in 2003, 2008 and 2009, for misleading the public through use of television advertisements which overstate the efficacy of YAZ and/or Yasmin and minimize serious risks associated with the drug.

38. The use of YAZ/Yasmin has a prothrombotic effect resulting in the development of thromboses, such as pulmonary emboli and deep vein thrombosis.

39. Defendants ignored the correlation between the use of the YAZ/Yasmin and the increased risk of developing thromboses, despite the wealth of scientific and medical evidence available.

40. The use of drospirenone, a diuretic, in YAZ/Yasmin creates unique and dangerous risks compared to other oral contraceptives. These risks include heart arrhythmias, myocardial infarctions, and other adverse cardiovascular events, including sudden death, stroke, transient ischemic attack, embolisms, blood clots, kidney and/or gallbladder disease.

41. Drospirenone acts as a diuretic, where it goes into the kidney and blocks aldosterone, a hormone that increases the reabsorption of sodium and water and secretes potassium, causing dehydration.

42. The use of drospirenone in YAZ/Yasmin and the blockage of aldosterone causes an imbalance in electrolytes by reducing sodium, a condition known as hyponatremis, and increasing potassium, a condition known as hyperkalemia, which may lead to serious and potentially fatal conditions known as hyperkalemia arrhythmia, myocardial infarctions, stroke, transient ischemic attacks, blood clots, embolisms, and/or sudden death.

43. Hyperkalemia arrhythmias are also associated with blood clots and/or thrombotic events such as a stroke, deep vein thrombosis, pulmonary embolism or heart attack.

44. The use of drospirenone in YAZ/Yasmin is also known to cause gallbladder disease, which could require surgical intervention.

45. Defendants did not provide adequate warnings to doctors, the healthcare community and the general public about the increase risk of serious adverse events that are described herein and that have been repeated by the medical community.

46. As a result of the foregoing, Plaintiff has sustained severe and permanent personal injuries.

CASE SPECIFIC FACTS

47. Plaintiff first began using YAZ/Yasmin on or about 2007. Plaintiff used YAZ/Yasmin as directed.

48. As a result of using Defendants' YAZ/Yasmin, Plaintiff became pregnant while on YAZ/Yasmin. Plaintiff further suffered gallbladder disease during pregnancy, and underwent surgical removal of her gallbladder on or about 2008. Plaintiff pregnancy was further complicated and resulted in a premature birth of her son. As a result of using Defendant's product YAZ/Yasmin, Plaintiff has sustained severe and permanent injuries, pain, suffering, and emotional distress, as well as other injuries.

49. The injuries and damages sustained by Plaintiff were caused by Defendants' YAZ/Yasmin.

FIRST CAUSE OF ACTION
NEGLIGENCE AND NEGLIGENCE PER SE

50. Plaintiff incorporates by reference all other paragraphs of this Complaint as if fully set forth herein and further alleges as follows:

51. Defendants, directly or indirectly, negligently and/or defectively designed, tested, inspected, manufactured, assembled, developed, labeled, sterilized, licensed, marketed, advertised, promoted, sold, packaged, supplied and/or distributed the drug YAZ or Yasmin.

52. At all relevant times, Defendants had a duty to users and/or consumers of YAZ/Yasmin, including Plaintiff, to exercise reasonable care in the design, testing, inspection, manufacture, assembly, development, labeling, sterilization, licensing, marketing, advertising, promotion, sale, packaging, supply and/or distribution of YAZ/Yasmin.

53. Defendants breached that duty and were negligent in the design, testing, inspection, manufacture, assembly, development, labeling, sterilization, licensing, marketing, advertising, promotion, sale, packaging, supply and/or distribution of YAZ/Yasmin in that: YAZ and Yasmin (drospirenone and ethinyl estradiol) was defective when put on the market by Defendants, that with such defect, YAZ/Yasmin was reasonably certain to be dangerous when put to normal use, and that Defendants failed to use reasonable care in designing or making YAZ/Yasmin or in inspecting it for defects. Specifically, Defendants breached their duty by, among other things:

a. Failing to include adequate warnings that would alert the medical, pharmaceutical and/or scientific communities, and users and/or consumers of the drug, including Plaintiff, to the potential risks and serious side effects of the drug;

b. Failing to adequately and properly test and inspect the drug before placing the drug on the market;

c. Failing to conduct sufficient testing and inspection of the drug which, if properly performed, would have shown that the drug had serious side effects, including, but not limited to, pulmonary embolism, deep venous thrombosis, heart attacks,

strokes and/or death, gall bladder disease and other serious and life threatening side effects;

d. Failing to adequately warn the medical, pharmaceutical and/or scientific communities, and users and/or consumers of the drug, including Plaintiff, of the potential risks and other serious side effects associated with the drug, including, among other things, pulmonary embolism, deep venous thrombosis, heart attacks, strokes and/or death, gall bladder disease and other serious and life threatening side effects;

e. Failing to provide adequate post-marketing warnings or instructions after Defendants knew or should have known of the scientific risks associated with the use of the drug;

f. Failing to recall and/or remove the drug from the stream of commerce despite the fact that Defendants knew or should have known of the defective and unreasonably dangerous nature of the drug, including the significant health risks associated with the use of the drug; and,

g. Encouraging misuse and overuse while failing to disclose the side effects of the drug to the medical, pharmaceutical and/or scientific communities, and users and/or consumers, including Plaintiff, in order to make a profit from sales.

54. Defendants knew or should have known that YAZ/Yasmin (drospirenone and ethinyl estradiol) causes unreasonably dangerous risks and serious side effects of which users and/or consumers of the drug, including Plaintiff, was not aware. Defendants nevertheless advertised, promoted, marketed, sold, distributed and/or supplied YAZ/Yasmin knowing that there were safer methods for contraception.

55. By reason of the foregoing, Plaintiff experienced and/or is at risk of experiencing serious and dangerous side effects including but not limited to, pulmonary embolism, deep venous thrombosis, heart attacks, strokes, and gall bladder disease as well as other severe and personal injuries which are permanent and lasting in nature, physical pain and mental anguish, including diminished enjoyment of life, as well as the need for lifelong medical treatment, monitoring and/or medications, and the fear of developing any of the above-named health consequences.

56. Plaintiff was damaged by the negligence and wanton and willful recklessness of the Defendants.

57. As a direct, legal, proximate and producing result of the negligence of the Defendants, Plaintiff sustained injuries as set forth above.

58. As a direct and proximate result of Defendants' acts and omissions, including their failure to exercise ordinary care in the design, formulation, manufacture, sale, and distribution of YAZ/Yasmin, Plaintiff ingested YAZ/Yasmin and suffered severe injuries, economic loss, and other damages, including but not limited to, cost of medical care, rehabilitation, lost income, and pain and suffering, for which Plaintiff is entitled to compensatory and equitable damages and declaratory relief in an amount to be proven at trial.

SECOND CAUSE OF ACTION
STRICT PRODUCTS LIABILITY—UNREASONABLY DANGEROUS DESIGN

59. Plaintiff incorporates by reference all other paragraphs of this Complaint as if fully set forth herein and further alleges as follows:

60. At all times relevant, Defendants have engaged in the business of designing, testing, inspecting, manufacturing, assembling, developing, labeling, sterilizing, licensing, marketing, advertising, promoting, selling, packaging, supplying, and/or distributing the drug

YAZ/Yasmin, which is defective and unreasonable dangerous to users and/or consumers of the drug, including Plaintiff.

61. YAZ/Yasmin was designed, tested, inspected, manufactured, assembled, developed, labeled, sterilized, licensed, marketed, advertised, promoted, sold, packaged, supplied and/or distributed by Defendants in a defective and unreasonably dangerous condition in ways which include, but are not limited to, one or more of the following:

a. When placed in the stream of commerce, the drug contained unreasonably dangerous design defects and was not reasonably safe or fit for its intended or reasonably foreseeable purpose or as intended to be used, thereby subjecting users and/or consumers of the drug, including Plaintiff, to risks which exceeded the benefits of the drug;

b. The drug was insufficiently tested;

c. The drug caused harmful side effects that outweighed any potential utility;

d. The drug was not accompanied by adequate labeling or instructions for use to fully apprise the medical, pharmaceutical and/or scientific communities, and users and/or consumers of the drug, including Plaintiff, of the potential risks and serious side effects associated with its use; and,

e. In light of the potential and actual risk of harm associated with the drug's use, a reasonable person who had actual knowledge of this potential and actual risk of harm would have concluded that YAZ/Yasmin should not have been marketed in that condition.

62. At all times the drug YAZ/Yasmin was designed, tested, inspected, manufactured, assembled, developed, labeled, sterilized, licensed, marketed, advertised, promoted, sold,

packaged, supplied and/or distributed, it was expected to reach, and did reach, users and/or consumers of the drug across the United States, including Plaintiff, without substantial change in the defective and unreasonably dangerous condition in which it was sold.

63. Plaintiff used YAZ/Yasmin for its intended or reasonably foreseeable purpose.

64. As a direct and proximate result of the defective and unreasonably dangerous design of YAZ/Yasmin, Plaintiff suffered severe injuries, economic loss, and other damages, including but not limited to, cost of medical care, rehabilitation, lost income, and pain and suffering, for which Plaintiff is entitled to compensatory and equitable damages and declaratory relief in an amount to be proven at trial.

THIRD CAUSE OF ACTION
STRICT PRODUCTS LIABILITY—FAILURE TO WARN

65. Plaintiff incorporates by reference all other paragraphs of this Complaint as if fully set forth herein and further alleges as follows:

66. YAZ/Yasmin was defective and unreasonably dangerous when it left the possession of Defendants in that it contained insufficient warnings to alert the medical, pharmaceutical and/or scientific communities, and users and/or consumers of the drug, including Plaintiff, to the dangerous risks and reactions associated with YAZ/Yasmin when used for its intended or reasonably foreseeable purpose. Those dangerous risks and reactions included, but were not limited to, pulmonary embolism, deep venous thrombosis, heart attacks, strokes and/or death, gall bladder disease and other serious and life threatening side effects.

67. Plaintiff used the drug for its intended or reasonably foreseeable purpose.

68. Plaintiff could not have discovered any defect in the drug through the exercise of care.

69. Defendants, as manufacturers of a prescription drug, are held to the level of knowledge of an expert in the field.

70. The warnings given by Defendants were not accurate or clear and/or were ambiguous.

71. Defendants had a continuing duty to warn the medical, pharmaceutical and/or scientific communities, and users and/or consumers of the drug, including Plaintiff, of the potential risks and serious side effects associated with the use of YAZ/Yasmin.

72. As a direct and proximate result Defendant's failure to warn, Plaintiff sustained injuries as asserted forth above, for which Plaintiff is entitled to compensatory and equitable damages and declaratory relief in an amount to be proven at trial.

FOURTH CAUSE OF ACTION
BREACH OF EXPRESS WARRANTY

73. Plaintiff incorporates by reference all other paragraphs of this Complaint as if fully set forth herein and further alleges as follows:

74. Defendants made express representations to the consuming public at large through their aggressive marketing and advertising campaigns relative to their product, YAZ/Yasmin.

75. Defendants, through their sales representatives, made representations of the safety and efficacy of their product, YAZ/Yasmin.

76. YAZ/Yasmin does not conform to the express representations made through Defendants' advertising and marketing efforts.

77. YAZ/Yasmin does not conform to the express representations made by Defendants' agents/sales representatives.

78. Defendants' conduct in this matter was a contributing cause of injuries and damages suffered by Plaintiff, for which Plaintiff is entitled to compensatory and equitable damages and declaratory relief in an amount to be proven at trial.

FIFTH CAUSE OF ACTION
BREACH OF IMPLIED WARRANTIES

79. Plaintiff incorporates by reference all other paragraphs of this Complaint as if fully set forth herein and further alleges as follows:

80. At the time that Defendants designed, tested, inspected, manufactured, assembled, developed, labeled, sterilized, licensed, marketed, advertised, promoted, sold, packaged, supplied and/or distributed the drug YAZ/Yasmin, Defendants knew of the intended, reasonably foreseeable and/or ordinary use of YAZ/Yasmin, and impliedly warranted the drug to be of merchantable quality and safe and fit for such use.

81. Plaintiff, in ingesting YAZ/Yasmin, reasonably relied upon the skill and judgment of Defendants as to whether YAZ/Yasmin was of merchantable quality and safe and fit for its intended, reasonable foreseeable and/or ordinary use.

82. In breach of the implied warranty given by Defendants, YAZ/Yasmin was not of merchantable quality or safe or fit for its intended, reasonably foreseeable, and/or ordinary use because the product was and is unmerchantable, in a defective condition and unreasonably dangerous and unfit for the intended, reasonably foreseeable and/or ordinary purpose for which it was intended as described above.

83. In breach of the implied warranty given by Defendants, YAZ/Yasmin was not of merchantable quality or safe or fit for its intended, reasonably foreseeable and/or ordinary use because, among other things:

a. Use of YAZ/Yasmin carried a risk of, among other things, pulmonary embolism, deep venous thrombosis, heart attacks, strokes and/or death, gall bladder disease and other serious and life-threatening side effects;

b. Defendants failed to include adequate warnings with the drug that would alert the medical, pharmaceutical and/or scientific communities, and users and/or consumers of the drug, including Plaintiff, of the potential risks and serious side effects of the drug;

c. Defendants failed to provide adequate post-marketing warnings or instructions after Defendants knew or should have known of the potential risks and serious side effects associated with the use of the drug, and,

84. As a direct and proximate result of Defendants' breach of warranty, Plaintiff sustained injuries as set forth above, for which Plaintiff is entitled to compensatory and equitable damages and declaratory relief in an amount to be proven at trial.

SIXTH CAUSE OF ACTION
FRAUDULENT MISREPRESENTATION

85. Plaintiff incorporates by reference all other paragraphs of this Complaint as if fully set forth herein and further alleges as follows:

86. Defendants falsely and fraudulently represented to the medical and healthcare community, and to Plaintiff and/or the FDA, and/or the public in general, that YAZ/Yasmin had been tested and was found to be safe and/or effective for its indicated use.

87. That representations made by Defendants were, in fact, false.

88. When said representations were made by Defendants, they knew those representations to be false and they willfully, wantonly and recklessly disregarded whether the representations were true.

89. These representations were made by said Defendants with the intent of defrauding and deceiving Plaintiff, the public in general, and the medical and healthcare community in particular, and were made with the intent of inducing the public in general, and the medical and healthcare community in particular, to recommend, dispense and/or purchase YAZ/Yasmin for use as a contraceptive, all of which evinced a callous, reckless, willful, depraved indifference to the health, safety and welfare of Plaintiff.

90. At the time the aforesaid representations were made by the Defendants and, at the time Plaintiff used YAZ/Yasmin, Plaintiff was unaware of the falsity of said representations and reasonably believed them to be true.

91. In reliance upon said representations, Plaintiff was inclined to and did use YAZ/Yasmin, thereby sustaining severe and permanent physical injuries, and/or being at an increased risk of sustaining severe and permanent personal injuries in the future.

92. Defendants knew and were aware or should have been aware that YAZ/Yasmin had not been sufficiently tested, was defective in nature, and/or that it lacked adequate and/or sufficient warnings.

93. Defendants knew or should have known that YAZ/Yasmin had a potential to, could, and would cause severe and grievous injury to the users of said product, and that it was inherently dangerous in a manner that exceeded any purported, inaccurate, and/or down-played warnings.

94. Defendants brought YAZ/Yasmin to the market, and acted fraudulently, wantonly, and maliciously to the detriment of the Plaintiff.

95. By reason of the foregoing, Plaintiff experienced and/or is at risk of experiencing serious and dangerous side effects including but not limited to, pulmonary embolism, deep

venous thrombosis, heart attacks, strokes, gall bladder disease, as well as other severe and personal injuries which are permanent and lasting in nature, physical pain and mental anguish, including diminished enjoyment of life, as well as the need for lifelong medical treatment, monitoring and/or medications, and fear of developing any of the above-named health consequences.

96. As a result of the foregoing acts and omissions, Plaintiff requires and/or will require more healthcare and services and did incur medical, health, incidental and related expense. Plaintiff is informed and believes and further alleges that Plaintiff will in the future be required to obtain further medical and/or hospital care, attention, and services. Plaintiff is entitled to compensatory and equitable damages and declaratory relief in an amount to be proven at trial.

SEVENTH CAUSE OF ACTION
FRAUDULENT CONCEALMENT

97. Plaintiff incorporates by reference all other paragraphs of this Complaint as if fully set forth herein and further alleges as follows:

98. At all times during the course of dealing between Defendants and Plaintiff and/or Plaintiff's healthcare providers, and/or the FDA, Defendants misrepresented the safety of YAZ/Yasmin for its intended use.

99. Defendants knew or were reckless in not knowing that its representations were false.

100. In representations to Plaintiff and/or Plaintiff's healthcare providers and/or the FDA, Defendants fraudulently concealed and intentionally omitted the following material information:

a. That YAZ/Yasmin is not as safe as other available contraceptives;

b. That the risks of adverse events with YAZ/Yasmin was higher than those with other available contraceptives;

c. That the risks of adverse events with YAZ/Yasmin was not adequately tested and/or known by Defendants;

d. Plaintiff was put at risk of experiencing serious and dangerous side effects including but not limited to, pulmonary embolism, deep venous thrombosis, heart attacks, strokes, gall bladder disease as well as other severe and personal injuries which are permanent and lasting in nature, physical pain and anguish;

e. That patients needed to be monitored more regularly than normal while using YAZ/Yasmin;

f. That YAZ/Yasmin was manufactured, marketed, produced, and distributed negligently;

g. That YAZ/Yasmin was manufactured, marketed, produced, and distributed defectively;

h. That YAZ/Yasmin was manufactured, marketed, produced, and distributed improperly;

i. That YAZ/Yasmin was designed negligently;

j. That YAZ/Yasmin was designed defectively;

k. That YAZ/Yasmin was designed improperly;

101. Defendants were under a duty to disclose to Plaintiff and/or her physicians, hospitals, healthcare providers, and/or the FDA the defective nature of YAZ/Yasmin.

102. Defendants had sole access to material facts concerning the defective nature of the product and its propensity to cause serious and dangerous side effects, and hence, cause damage to persons who used YAZ/Yasmin, including the Plaintiff in particular.

103. Defendants' concealment and omissions of material facts concerning, inter alia, the safety of use of YAZ/Yasmin was made purposefully, willfully, wantonly, and/or recklessly, to mislead. Plaintiff and/or her physicians, hospitals and/or healthcare providers, in reliance, continued use of YAZ/Yasmin, and actions thereon, and to cause them to purchase, recommend, and/or dispense YAZ/Yasmin and/or use the drug.

104. Defendants knew that Plaintiff and/or her physicians, hospitals, healthcare providers, and/or the FDA had no way to determine the truth behind Defendants' concealment and omissions, and that these included material omissions of fact surrounding YAZ/Yasmin as set forth herein.

105. Plaintiff, as well as their doctors, healthcare providers, and/or hospitals reasonably relied on facts revealed with negligently, fraudulently and/or purposefully did not include facts that were concealed and/or omitted by Defendants.

106. By reason of the foregoing, Plaintiff experienced and/or is at risk of experiencing serious and dangerous side effects including but not limited to, bilateral pulmonary embolism, deep venous thrombosis, heart attacks, strokes, gall bladder disease as well as other severe and personal injuries which are permanent and lasting in nature, physical pain and mental anguish, including diminished enjoyment of life, as well as the need for lifelong medical treatment monitoring and/or medications, and fear of developing any of the above-named health consequences.

107. As a result of the foregoing acts and omissions, Plaintiff requires and/or will require more healthcare services and did incur medical, health, incidental and related expenses.

108. Plaintiff is entitled to compensatory and equitable damages and declaratory relief in an amount to be proven at trial.

EIGHTH CAUSE OF ACTION
NEGLIGENT MISREPRESENTATION

109. Plaintiff incorporates by reference all other paragraphs of this Complaint as if fully set forth herein and further alleges as follows:

110. Defendants had a duty to represent to the medical and healthcare community, and to the Plaintiff, the FDA and/or the public in general that YAZ/Yasmin had been tested and found to be safe and effective for its intended use.

111. The representations made by Defendants were, in fact, false.

112. Defendants failed to exercise ordinary care in the representation of YAZ/Yasmin, while involved in its manufacture, sale, testing, quality assurance, quality control, and/or distribution into interstate commerce, in that Defendants negligently misrepresented YAZ/Yasmin's high risk of unreasonable, dangerous side effects.

113. Defendants breached their duty in representing YAZ/Yasmin serious side effects to the medical and healthcare community, to the Plaintiff, the FDA, and/or the public in general.

114. By reason of the foregoing, Plaintiff experienced and/or is at risk of experiencing serious and dangerous side effects including but not limited to, bilateral pulmonary embolism, deep venous thrombosis, heart attacks, strokes, gall bladder disease as well as other severe and personal injuries which are permanent and lasting in nature, physical pain and mental anguish, including diminished enjoyment of life, as well as the need for lifelong medical treatment

monitoring and/or medications, and fear of developing any of the above-named health consequences.

115. As a result of the foregoing acts and omissions, Plaintiff requires and/or will require more healthcare services and did incur medical, health, incidental and related expenses.

116. Plaintiff is entitled to compensatory and equitable damages and declaratory relief in an amount to be proven at trial.

NINTH CAUSE OF ACTION
FRAUD AND DECEIT

117. Plaintiff incorporates by reference all other paragraphs of this Complaint as if fully set forth herein and further alleges as follows:

118. Defendants recklessly, knowingly, intentionally, and fraudulently misrepresented to the medical, pharmaceutical and/or scientific communities, and users and/or consumers of the drug, including Plaintiff, the safety and efficacy of the drug and/or recklessly, knowingly, intentionally and fraudulently concealed from the medical, pharmaceutical and/or scientific communities, and users and/or consumers of the drug, including Plaintiff, material, adverse information regarding the safety and efficacy of YAZ/Yasmin.

119. Defendants misrepresentations were communicated to the medical, pharmaceutical and/or scientific communities, and users and/or consumers of the drug, including Plaintiff, with the intent that they reach users and/or consumers of the drug, including Plaintiff.

120. Defendants made the misrepresentations and/or actively concealed information concerning the safety and efficacy of the drug with the intention and specific desire that the medical, pharmaceutical and/or scientific communities, and users and/or consumers of the drug, including Plaintiffs, would rely on such in selecting YAZ/Yasmin as a contraceptive.

121. Defendants made these misrepresentations and/or actively concealed information concerning the safety and efficacy of YAZ/Yasmin in its labeling, advertising, product inserts, promotional materials or other marketing efforts.

122. Defendants made these misrepresentations and actively concealed adverse information at a time when Defendants knew or should have known that its drug product had defects, dangers, and characteristics that were other than what Defendants had represented to the medical, pharmaceutical and/or scientific communities, and users and/or consumers of the drug, including Plaintiff. Specifically, Defendants misrepresented to and/or actively concealed from the medical, pharmaceutical and/or scientific communities, and users and/or consumers of the drug, including Plaintiff, that:

a. There had been insufficient studies regarding the safety and efficacy of the drug;

b. The drug was fully and adequately tested, despite knowing that there had been insufficient or inadequate testing of the drug;

c. Prior studies, research, reports and/or testing had been conducted linking the use of the drug to serious prothrombotic reactions, including, but not limited to, adverse cardiovascular events such as pulmonary embolism, heart attacks, strokes and vascular events such as deep venous thrombosis, and gall bladder disease;

d. Defendant knew or should have known of reports of increased prothrombotic events associated with the use of the drug; and,

e. Defendants knew or should have known of the greatly increased risk of developing pulmonary embolism, deep venous thrombosis, heart attacks and/or strokes, and gall bladder disease associated with use of YAZ/Yasmin; despite this, Defendants downplayed the risk of the drug.

123. The misrepresentations of and/or active concealment by Defendants were perpetuated directly and/or indirectly by Defendants, its sales representatives, employees, distributors, agents and/or detail persons.

124. The misrepresentations of and/or active concealment by Defendants constitute a continuing tort. Defendants continue to misrepresent the potential risks and serious side effects associated with the use of YAZ/Yasmin through their product inserts. Moreover, Defendants had a post-sale duty to warn the medical, pharmaceutical and/or scientific communities, and users and/or consumers of the drug, including Plaintiff, about the potential risks and serious side effects associated with the use of YAZ/Yasmin in a timely manner, yet they failed to provide such a warning.

125. Plaintiff justifiably relied on and/or was induced by the misrepresentations and/or active concealment of Defendants to purchase and ingest YAZ/Yasmin to her detriment.

126. As a direct and proximate result of the misrepresentations of Defendants, Plaintiff sustained injuries as set forth above. Plaintiff is entitled to compensatory and equitable damages and declaratory relief in an amount to be proven at trial.

TENTH CAUSE OF ACTION
UNJUST ENRICHMENT

127. Plaintiff incorporates by reference each and every paragraph of this Complaint as if fully set forth herein and further alleges as follows:

128. As the intended and expected result of their conscious wrongdoing, Defendants have profited and benefited from the purchase and implementation of YAZ/Yasmin by Plaintiff.

129. Defendants have voluntarily accepted and retained those profits and benefits, derived from Plaintiff, with full knowledge and awareness that, as a result of Defendants' fraud and other conscious and intentional wrongdoing, Plaintiff was not receiving a product of the

quality, nature, or fitness that had been represented by Defendants, or that Plaintiff, as a reasonable consumer, expected to receive.

130. By virtue of the conscious wrongdoing alleged above, Defendants have been unjustly enriched at the expense of Plaintiff, who is entitled in equity, and hereby seeks, the disgorgement and restitution of Defendants' wrongful profits, revenues and benefits, to the extent and in the amount deemed appropriate by the Court; and such other relief as the Court deems just and proper to remedy Defendants' unjust enrichment.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff prays for relief against Defendants, jointly and severally, as follows:

1. Compensatory damages according to proof, in excess of the amount required for federal diversity jurisdiction, and in an amount to fully compensate Plaintiff for all of Plaintiff's injuries and damages, both past and present;

2. Special damages according to proof, in excess of the amount required for federal diversity jurisdiction and in an amount to fully compensate Plaintiff for all of Plaintiff's injuries and damages, both past and present, including but not limited to, past and future medical expenses, costs for past and future rehabilitation and/or home health care, lost income, permanent disability, including permanent instability and loss of balance, and pain and suffering.

3. Double or triple damages as allowed by law;

4. Disgorgement of profits;

5. A full refund for all prescriptions paid;

6. Attorneys' fees, expenses, and costs of this action;

7. Pre-judgment and post-judgment interest in the maximum amount allowed by law; and

8. Such further relief as this Court deems necessary, just, and proper.

JURY DEMAND

Plaintiff demands trial by jury of all claims asserted in this Complaint.

Dated: February 17, 2012

LAW OFFICES OF CHARLES H. JOHNSON, PA

/s/ Charles H. Johnson

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